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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/927,046

08/09/2001

James McSwiggen

MBHB00-814-A  
(400/034US)

4737

20306 7590 04/24/2003

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EXAMINER

MCGARRY, SEAN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 04/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/927,046

Applicant(s)

MCSWIGGEN ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-60 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-21, 28-44, 47, 48, 51-60, drawn to a nucleic acid molecule that inhibits CLCA1 expression, classified in class 536, subclass 24.1.
- II. Claims 22-27, 45, 46, 49, and 50, drawn to a method of nucleic acid based therapy, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case CLCA1 may be inhibited by small molecule inhibitors which are patentably distinct from the nucleic acid inhibitors of Group I and also the nucleic acid inhibitors of Group I could be used in a method of gene function study which method is patentably distinct method from a method of treating disease, for example.

Group I is further restricted as follows:

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences recited in the claims are subject to restriction. The Commissioner has partially waived the

requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

The claims specifically claim ribozymes/antisense by SEQ ID NOS 1-100 or which are targeted to specific target sequences referenced by SEQ IDs. These nucleic acid molecules are targeted to and down regulate the expression of the CLCA1 gene. Although the ribozyme/antisense sequences claimed each target and modulate expression of the same gene, the instant sequences are considered to be unrelated, since each sequence claimed [including those targeting recited sequence targets] is structurally and functionally independent and distinct for the following reasons: each has a unique nucleotide sequence, each targets a different and specific region of a nucleic acid encoding CLCA1, and each, upon binding to a nucleic acid encoding CLCA1, down regulate the expression of the nucleic acid encoding CLCA1 to varying degree. Furthermore, a search of more than one (1) of the antisense/ribozyme sequences or target sequences therefore presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. In view of the foregoing, one (1) ribozyme/antisense sequence or target sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) ribozyme targeted to a sequence recited in claim 4, one (1) ribozyme sequence from claim 5 that corresponds to that sequence elected from claim 4, one antisense targeted

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to a sequence from claim 7 that corresponds with the sequences elected from claims 4 and 5; **or**, one antisense sequence from claim 8. It is noted that claims 29-34 recite sequences included in claim 4. Applicant should, upon election, indicate which claims from Group I above correspond to or embrace the specific sequence/sequences elected for examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

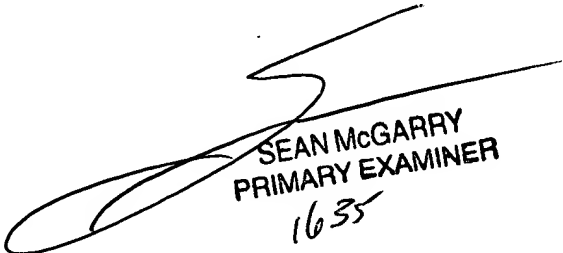
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM  
April 22, 2003

  
SEAN MCGARRY  
PRIMARY EXAMINER  
1635